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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,225	09/26/2003	Ivan Alferiev	RCHP-125US1	2873

23122 7590 07/11/2007
RATNERPRESTIA
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EXAMINER

VENCI, DAVID J

ART UNIT	PAPER NUMBER
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1641

MAIL DATE	DELIVERY MODE
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07/11/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/672,225

Applicant(s)

ALFERIEV ET AL.

Examiner

David J. Venci

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on March 12, 2007.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 4, 8-13, 15, 17, 18, 21 and 23-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-7, 14, 16, 19, 20 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-30 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on March 12, 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 01/22/04
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

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DETAILED ACTION

Examiner acknowledges Applicants' reply, filed March 12, 2007.

Election/Restrictions

In prior Office Action, claim 19 was withdrawn from consideration pursuant to 37 CFR 1.142(b) for allegedly being drawn to a nonelected species.

In response, Applicants argue that the "dithio group" of claim 19 is a "thiol-reactive group" as defined in the specification at p. 8, line 31 and elected under 3(b) of the Restriction/Election requirement of October 6, 2005. Applicants' argument is persuasive and, accordingly, claim 19 is rejoined.

Upon further review of amended claims 12 and 13, Examiner observes that the fluorophore fluorescent moiety of amended claims 12 and 13 does not appear to correspond to the fluorophore in claim 7 that Applicants elected, without traverse, in Applicants' reply filed November 2, 2005. Specifically, the fluorophore fluorescent moiety of amended claims 12 and 13 appears to require a disulfide bond, while the fluorophore elected in claim 7 does not have a disulfide bond. Claims 12 and 13 appear to be directed to a non-elected species and, accordingly, are withdrawn from further consideration pursuant to 37 CFR 1.142(b).

Upon further review of withdrawn claim 18, Examiner observes that claim 18, as amended, now appears to require a dithio group or a thiol-reactive group as defined in the specification at p. 8, line 31 and elected under 3(b) of the Restriction/Election requirement of October 6, 2005. However, claim 18 requires a fluorophore (*i.e.*, DTNB) that does not correspond to the fluorophore in claim 7 that Applicants elected,

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without traverse, in Applicants' reply filed November 2, 2005. Accordingly, claim 18 is direct to a non-elected species and remains withdrawn from further consideration pursuant to 37 CFR 1.142(b).

Claims 23-30 are drawn to a nonelected invention and were withdrawn from further consideration pursuant to 37 CFR 1.142(b) in prior Office Action. Claims 4, 8-11, 15, 17, 18 and 21 are drawn to nonelected species and were withdrawn from further consideration pursuant to 37 CFR 1.142(b) in prior Office Action.

Currently, claims 1-3, 5-7, 14, 16, 19, 20 and 22 are under examination.

Response to Amendment

The amendment filed March 12, 2007, does not comply with the requirements of 37 CFR 1.121(c) because Applicants have not accurately identified the status of the amended claims. Specifically, Applicants' amendment improperly identifies withdrawn claims 4, 8-11, 15, 17, 18 and 21 as "Currently Amended". Future correspondence must identify withdrawn claims with the status identifier "Withdrawn". In addition, future correspondence should identify amended withdrawn claims with the status identifiers like "Withdrawn—Currently amended" or "Withdrawn—Previously presented".

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Claim Rejections - 35 USC § 112 – first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter not described in the specification in a way so as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicants amend withdrawn claim 4 to require R² is a "divalent aromatic". Examiner is unable to locate support for this new limitation in Applicants' original specification.

Applicants are required to cancel new matter.

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Claim Rejections - 35 USC § 112 – second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 5-7, 14, 16, 19, 20 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the consecutive steps of "contacting" thereby "forming" a linking bond immediately followed by "cleaving the linking bond" is indefinite. The purpose of initially "forming" a linking bond in the overall method is not clear. One or more steps directed to doing something with the formed "linking bond" appear omitted from the claim.

In claim 5, the recitation of "FI-SH" is indefinite, wherein "FI-SH" = "compounds wherein FI comprises a fluorescein moiety". The orientation of "-SH" with respect to fluorescein is not clear.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness^{1,2} rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5-7, 14, 16, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pope & Knigge (US 5,399,501) in view of Melancon (US 4,922,113).

Pope & Knigge describe a method of determining a binding capacity (see Abstract, last sentence, "diagnostic binding assays") of a surface (see Title, "solid phase"), the method comprising the following claimed steps:

1. providing a surface (see e.g., col. 6, line 41, "alumina") comprising a first reactive moiety (see Fig. 4, product of first reaction);
2. contacting the surface (see Abstract, sixth sentence, "the solid phase is reacted with a disulfide compound to form a complex") with a fluorophore comprising a second reactive moiety (see col. 7, line 50, "N,N'-didansyl-L-cystine"), thereby
 - a. causing a reaction between the first and second reactive moieties (see Abstract, sixth sentence, "reacted");

¹ In the Supreme Court decision *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), the Court set forth factual inquiries establishing a background for determining obviousness under 35 U.S.C. 103(a). The factual inquiries include: (1) determining the scope and contents of the prior art; (2) ascertaining the differences between the prior art and the claims at issue; (3) resolving the level of ordinary skill in the pertinent art; and (4) considering objective evidence indicating obviousness or nonobviousness.

² The lack of objective evidence of nonobviousness in the instant application does not suggest "the level of ordinary skill in the pertinent art" is high.

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- b. forming a linking bond that binds the fluorophore to the surface (see Abstract, sixth sentence, "form a complex");
3. cleaving the linking bond (see Abstract, sixth sentence, "the complex is reacted with a reductant"), thereby liberating the fluorophore from the surface;

Pope & Knigge do not teach the claimed steps:

4. exposing the liberated fluorophore to exciting radiation;
5. measuring fluorescence from the liberated fluorophore
6. calculating binding capacity.

However, Melancon describe the general use of fluorescence measurements for monitoring coating processes (see Title and Abstract).

It would have been obvious to a person of ordinary skill to monitor Pope & Knigge's method using fluorescence because Melancon reiterates that, in addition to correlating fluorescence to binding capacity (*i.e.*, "coating weights or thicknesses"), fluorescence measurements also allow detection of coat uniformity and defects (see Abstract).

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pope & Knigge (US 5,399,501) and Melancon (US 4,922,113) as applied to claims 1, 2 and 20, and further in view of Burns *et al.*, 56 J. ORG. CHEM. 2648 (1991).

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Pope & Knigge and Melancon describe a method of determining a binding capacity of a surface as substantially described, *supra*, and incorporated herein.

Pope & Knigge and Melancon do not describe a tris(2-carboxyethyl)phosphine (hereinafter "TCEP") reducing agent.

However, Burns *et al.* describe the general use of TCEP for selective reduction of disulfides (see Title).

It would have been obvious for a person of ordinary skill in the art to modify the method of Pope & Knigge and Melancon by using TCEP because Burns *et al.* discovered that TCEP reduces disulfides "rapidly and completely" at acidic pH (see Abstract), said acidic pH being necessary to prevent thiolate-disulfide interchange (see p. 2649, col. 1, last paragraph).

Response to Arguments

Claim Rejections - 35 USC § 112 – second paragraph

In prior Office Action, claim 5 was rejected under 35 U.S.C. 112, second paragraph, because the recitation of "FI-SH" is indefinite, wherein "FI-SH" = "compounds wherein FI comprises a fluorescein moiety". The orientation of "-SH" with respect to fluorescein is not clear.

In response, Applicants argue that "numerous examples explicitly showing the orientation of -SH with respect to the fluorescent moiety are shown throughout the application" (see Applicants' reply, paragraph bridging pp. 12-13).

Applicants' argument is not persuasive because persons of ordinary skill may not be so imaginative as to be able to import into claim 5 whatever clarifying structural details from "throughout the application" to arrive at the definition of "FI-SH" as intended in Applicants' reply.

Prior Art Claim Rejections

In prior Office Action, claims 1-3, 5-7, 12-14, 16 and 20 were rejected under 35 U.S.C. 102(b) as being anticipated by Pope & Knigge (US 5,399,501). In addition, claim 22 was rejected under 35 U.S.C. 103(a) as being unpatentable over Pope & Knigge (US 5,399,501) in view of Burns *et al.*, 56 J. ORG. CHEM. 2648 (1991).

In response, Applicants amend independent claim 1 to require steps of "exposing" and "measuring" liberated fluorophore. Applicants' amendment and relevant argumentation is sufficient to overcome these rejections. Accordingly, these rejections are withdrawn.

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Conclusion


No claims are allowable at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

David J Venci
Examiner
Art Unit 1641

djv


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